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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,010	10/12/2000	YOSHIAKI HATA	15162/02600	6171

24367 7590 05/13/2005

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EXAMINER

BARTON, JEFFREY THOMAS

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/689,010

Applicant(s)

HATA, YOSHIAKI

Examiner

Jeffrey T. Barton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-29 is/are pending in the application.
- 4a) Of the above claim(s) 9-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed on 31 March 2005 does not place the application in condition for allowance.

Drawings

2. The Examiner acknowledges Applicant's request for a Notice of Draftperson's Patent Drawing Review. While the USPTO no longer has Draftspeople on staff, the Examiner accepts the formal drawings as originally submitted on 12 October 2000.

***Status of Objections and Rejections Pending Since the
Office Action of 28 December 2004***

3. All rejections of claims 6 and 7 are withdrawn due to cancellation of the claims.
4. The objection to claim 2 is withdrawn due to Applicant's amendment.
5. The rejection of claims 1, 2, and 4 under 35 U.S.C. §102(e) as anticipated by Kennedy is withdrawn due to Applicant's amendment.
6. The rejection of claim 1 under 35 U.S.C. §102(b) as anticipated by Pace is maintained.
7. The rejection of claims 1 and 8 under 35 U.S.C. §102(b) as anticipated by Manz et al is withdrawn due to Applicant's amendment.
8. The rejection of claims 1 and 8 under 35 U.S.C. §102(b) as anticipated by Kaltenbach is withdrawn due to Applicant's amendment.

9. The rejection of claims 2-4 under 35 U.S.C. §103(a) as obvious over Manz et al in view of Kricka et al is withdrawn due to Applicant's amendment.
10. The rejection of claim 3 under 35 U.S.C. §103(a) as obvious over Kennedy is withdrawn due to Applicant's amendment.
11. The rejection of claim 5 under 35 U.S.C. §103(a) as obvious over Kennedy in view of Weigl et al is withdrawn due to Applicant's amendment.
12. The rejection of claim 5 under 35 U.S.C. §103(a) as obvious over Kennedy in view of Swerdlow et al is withdrawn due to Applicant's amendment.
13. The rejection of claim 5 under 35 U.S.C. §103(a) as obvious over Pace in view of either Weigl et al or Swerdlow et al is maintained.

Claim Rejections - 35 USC § 102

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
15. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pace.
Pace discloses a chip comprising a channel with analytes passing therethrough. (Figure 3; Column 3, line 52 - Column 4, line 11); an optical element (Plate 38 functions as a window) facing the channel to receive light from the analytes (Fluorescence; Column 8, lines 11-21), said optical element forming a part of the internal surface of the channel. (Figure 3); said microchip further comprising as deflecting elements (The constriction of the channel caused by the material of electrode 12, visible in Figure 3,

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would inherently cause a degree of deflection of analyte objects as they pass) for approximating the analytes in said channel to said optical element: a first electrode that faces said channel, in the vicinity of the optical element (Figure 1, electrode 12 closest to detector 22; one face of the electrode faces the channel, as shown in Figure 3); a second electrode provided to face said channel (Figure 1, any electrode 12 shown to the left of the electrode indicated above) in a position to said first electrode (Upstream of the first electrode, this reads on the claim limitation), at an upstream side of said optical element with respect to the traveling direction of the analyte (Figure 1); wherein the analyte is capable of being approximated to said optical element by applying a predetermined electric field between the first and second electrodes. (Column 9, lines 13-37)

Regarding the limitations of the claim found in lines 7-8 and 14-15, as amended), the Examiner reads "approximating" and "approximated to" to broadly mean causing or caused to move toward. This implies no motion particularly perpendicular or parallel to the direction of channel propagation, and any type of motion toward the optical element would read on the claim. The disclosure of Pace describing separation and movement of the analytes to and past the detector, caused by application of electric fields between electrodes (Column 9, lines 13-37), is considered to meet these limitations.

Claim Rejections - 35 USC § 103

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace in view of Kennedy.

Pace discloses a device as described above in addressing claim 1.

Relevant to claim 2, Pace also discloses a portion of the internal surface of the channel being defined by a groove formed on a first surface of a substrate. (e.g. Figure 3; Column 7, lines 14-32) This substrate (A silicon wafer) has a second surface opposed to the first surface.

Relevant to claim 4, Pace discloses a cover plate covering the groove (Figure 3, plate 38)

Pace does not explicitly disclose a through hole connecting a bottom of the groove to the second surface, wherein said optical element is provided in said through hole.

Kennedy discloses a microfluidic device comprising a groove disposed on a first surface, with a through hole connecting the bottom of the groove to a second surface, and the optical element being provided in said hole. (Column 7, lines 33-65; the hole in Kennedy's device passes through both substrates, providing the window in the case of opaque substrate materials. Nevertheless, it does connect the bottom of the groove to the second surface, and therefore reads on the claimed device.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pace by providing a through hole through

the plates of the device for the detection window, as taught by Kennedy, because it would eliminate any concerns about absorbance, scattering, or other interference from the substrate. Furthermore, choice of a particular detector geometry (i.e. irradiation and detection above the channel, shown by Pace, or irradiation from above, and detection below, shown by Kennedy) is a design choice that was well within the abilities of one having ordinary skill in the art.

Regarding claim 3, neither Kennedy nor Pace explicitly disclose a tapered through hole.

However, it is well within the abilities of one having ordinary skill in the art to select a shape suitable for the hole that accommodates the detection window. For instance, in *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966), the court held that the configuration (i.e. shape) of the claimed object was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.

Furthermore, both Pace (Column 5, lines 35-48) and Kennedy (Column 3, line 65 - Column 4, line 4) disclose forming the microfluidic devices from silicon, and conventional etching techniques (e.g. KOH) typically attack silicon anisotropically, resulting in tapering pits, trenches, or holes.

18. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace in view of Manz et al and Kricka et al.

Pace discloses a device as described above in addressing claim 1.

Relevant to claim 2, Pace also discloses a portion of the internal surface of the channel being defined by a groove formed on a first surface of a substrate. (e.g. Figure 3; Column 7, lines 14-32) This substrate (A silicon wafer) has a second surface opposed to the first surface.

Relevant to claim 4, Pace discloses a cover plate covering the groove (Figure 3, plate 38)

Pace does not explicitly disclose a through hole connecting a bottom of the groove to the second surface, wherein said optical element is provided in said through hole.

Relevant to claim 2, Manz et al teach the construction of a detector (for incorporation into miniaturized separation systems (Column 2, lines 58-60), in which a substrate (Figure 4, plate 5) has a second surface (top, as shown in Figure 4) opposed to a first surface and has a through hole (11) with an optical element (13) disposed therein.

Relevant to claim 3, Manz et al disclose the through hole (11) having a tapered shape. (Figure 4)

Relevant to claim 2, Manz et al do not explicitly disclose the channel being defined in part by a groove on the first surface (interior) of substrate (5).

Kricka et al disclose formation of channel grooves in a microfluidic device on the same substrate as through-holes that provide access to the channels. (i.e. the channel is defined by a groove on one surface and holes connect the bottom of the groove to the opposing surface - see Figures 2 and 4) The device of Kricka et al is made of the same material (crystalline silicon) as is preferred by both Manz et al and Pace.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pace by replacing his detector with an on-chip detector cell, as taught by Manz, because Manz teaches its effectiveness in increasing detection sensitivity in miniaturized separation apparatuses (Pace is an example) by providing an increased detection path length. (Column 2, lines 49-60)

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the combined device of Pace and Manz et al by fabricating the channel on the inward-facing surface of substrate 5 (Manz), instead of plate 6, as taught by Kricka et al, because it would simplify device construction by allowing channel paths to be directly defined by through hole locations (i.e. channel etching could be guided by hole locations after through-hole etching), and eliminating concerns over the alignment of plates relative to each other. Furthermore, the choice of which plate(s) to use in providing through holes for communication with the channel would have been within the level of ordinary skill in the art.

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19. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pace in view of either Weigl et al or Swerdlow et al.

Pace discloses a device as described above in addressing claim 1.

Pace does not explicitly disclose the optical element comprising a condenser lens.

Weigl et al disclose a detector comprising a condenser lens useful in combination with microfluidic devices. (Figure 2, lens 50, cartridge 34 corresponds to the microfluidic device - see background section; also Column 4, lines 16-40)

Swerdlow et al describe a detector comprising a lens that "condenses" light emitted over a range of angles into a converging beam, wherein the detector is used in combination with a capillary flow cell. (Figure 3, objective lens)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pace by replacing his detector with the detector taught by Weigl et al, because they teach its usefulness in detecting multiple analytes at multiple wavelengths (Column 3, lines 7-15), and electrophoresis devices, such as that of Pace, are often used for analysis of multicomponent samples.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pace by replacing their detector with the detector described by Swerdlow et al, because they teach its extremely high sensitivity.

(Abstract)

In these rejections, given the open language of the claims (i.e. "comprising") the limitation "optical element having a surface forming part of the internal surface of the channel" is read broadly such that a detection system comprising both a window that forms part of the channel's internal surface and a condenser lens is held to read on the claim limitations.

20. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pace in view of Manz et al.

Pace discloses a device as described above in addressing claim 1.

Pace does not explicitly disclose a device comprising a light guide for guiding light from an external source to a prescribed area of the channel, wherein the optical element is provided at the prescribed area.

Manz et al teaches the construction of a detector for incorporation into miniaturized separation systems (Column 2, lines 58-60) comprising a light guide (Figure 4, Fiber 12) for guiding a light from an external source to an area of the channel (the portion between Fibers 13 and 13), wherein the element (13) is provided at the prescribed area.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pace by replacing his detector with an on-chip detector cell, as taught by Manz et al, because Manz et al teach its effectiveness in increasing detection sensitivity in miniaturized separation apparatuses (Pace is an example) by providing an increased detection path length. (Column 2, lines 49-60)

Response to Arguments

21. Applicant's arguments, see Amendment (Page 10, 3rd paragraph - Page 14, 1st full paragraph), with respect to the rejections using Manz et al, Kennedy, and Kaltenbach as primary references have been fully considered and are persuasive. These rejections have been withdrawn.

22. Applicant's arguments (Page 9, 5th full paragraph - Page 10, 2nd paragraph) regarding the rejections using Pace as the primary reference have been fully considered but they are not persuasive.

Applicant describes claim 1, as amended, as being limited to first and second electrode deflecting elements for approximating the object in the channel to the optical element, then describes the operation of the device, describing the electrodes as positioned opposite each other. However, there is no explicit recitation of such opposite placement of the electrodes in claim 1. The second electrode is described as being "in a position to said first electrode", which essentially does not limit the location of the second electrode. The Examiner's position is that the second electrode could be located anywhere within the device and still meet this limitation.

Applicant argues that the electrodes disclosed by Pace are not deflecting elements for approximating an object to an optical element, that the electrodes of Pace are not in the configuration required by claim 1. (Amendment Page 10, 1st paragraph)

The Examiner disagrees for the following reasons. First, given a reasonably broad reading of "deflecting elements", the electrodes of Pace read on this limitation, since they would provide a constriction in the channel, as can be seen in the illustration of Figure 3, and inferred from the method of device construction given by Pace at Column 7, lines 14-53. Steps 6 and 7 of this method make no mention of disposing the electrodes in recesses within the channel, which would mean that electrodes of any thickness would protrude into the channel. Any such protrusion would inherently lead to deflection of objects within a stream of passing liquid.

Second, the electrodes of Pace provide an electric field to drive the electrophoretic separation, which carries the analytes past the detector. (e.g. Column 9, lines 13-37), which means that during the separation, the electrodes will cause the motion of analyte objects towards the detector. As stated in the rejection above, the Examiner reads "approximating" and "approximated to" to broadly mean causing or caused to move toward. This implies no motion particularly perpendicular or parallel to the direction of channel propagation, and any type of motion toward the optical element would read on the claim. Therefore, the disclosure of Pace meets the limitations that the electrodes be "for approximating said object in said channel to said optical element" and the objects being capable of "being approximated to said optical element by applying a predetermined electric field between [the electrodes]"

Applicant further argues that the electrodes of Pace are sequential and completely encircle the channel, and thus cannot be opposite one another as required by claim 1. (Amendment, Page 10, 1st paragraph) The Examiner's position is that Claim

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1 does not require the electrodes to be opposite each other. The second electrode is described as being "in a position to said first electrode", which essentially does not limit the location of the second electrode. The second electrode could be located anywhere within the device and still meet this limitation.

Applicant also contrasts the motion caused by the electrodes of Pace (along the channel) with that caused by the device of claim 1, which is characterized as being deflection perpendicular to the length of the channel. (Amendment Page 10, 1st paragraph) The Examiner agrees that the motion caused by applying an electric field in the device of Pace is indeed along the channel length, but there is no explicit recitation in claim 1 that would preclude such lengthwise motion from reading on the claim. Perpendicular motion caused by electrodes disposed across the width/depth of a channel, while certainly envisaged in the instant specification, is not required by the language of claim 1.

Therefore, since Pace meets all limitations given in claim 1, it is considered to anticipate the claim.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB

April 29, 2005

A handwritten signature in black ink, appearing to read 'Nam Nguyen', with a large, stylized loop at the end.

NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700